

REMARKS/ARGUMENTS

By this Amendment, the specification and claims 8 and 10 are amended and claim 11 is added. Claims 8 and 10-11 are pending. Claim 11 is added to recite the cutter limitation of apparatus claim 8 in a method claim. Support for claim 11 is apparent in the disclosure at, e.g., pages 10-11. The specification is amended to provide a more accurate translation of the corresponding French-language passage on page 6, line 25 of the PCT application (published as WO 98/44911) on which the present application is based.

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

Rejections under 35 U.S.C. 112

Claim 8 stands rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regard as the invention. This rejection is respectfully traversed.

This rejection is based on the Examiner's unsupported assertion that spheroid particles cannot be formed by the mere act of chopping a filament because "the resulting shape is expected to be discoid and not a spheroid, to get a spheroid, there should be an additional step to be obtained from a discoid."

The claims recite the term "spheroid" because it accurately describes the shape of particles obtained by the method of the invention and with the apparatus of the invention. As disclosed in the specification at page 6, lines 7-12, "...it is possible to obtain the particles in accordance with the invention directly in spheroidal form at the exit from the die provided that the cutters in the chopping device at the exit from the die have the shape described later and

shown in figures 1 and 2.” The shape of the cutters adapted to provide spheroidal particles is specified in claim 8.

The particles are not discoid as defined in the Office Action, and therefore there is no indefiniteness in the language employed by Applicants.

Accordingly, reconsideration and withdrawal of the indefiniteness rejection of claim 8 are respectfully requested.

The indefiniteness rejection of claim 10 is obviated by the foregoing amendment introducing the term “organism” with the article “an”. Accordingly, reconsideration and withdrawal of the indefiniteness rejection of claim 10 are respectfully requested.

Rejection under 35 U.S.C. § 103

Claims 8 and 10 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Oshlack et al. (WO 96/14058) in view of Martin et al. (US 5811186). This rejection is respectfully traversed.

Claim 8 is directed to an apparatus for making spheroid particles, wherein said apparatus comprises cutters in the form of blades having a first and a second face parallel with one another, the first face being inclined toward the second face, thus forming a cutting edge, the second face being recessed so as to leave a strip of a width of less than 1 mm which comprises the cutting edge, whereby the particles obtained by chopping the extruded filaments with the cutters are spheroidal without any additional spheroidal shaping step.

Oshlack et al. discloses next to nothing about how one can obtain spheroidal particles from extruded filaments. The Examiner cites Fig. 9 of Oshlack et al. in support of the rejection,

but the conventional circular saw depicted in that figure does not read on the cutters of claim 8. It is the specific limitations of the cutters of claim 8, such as the recessed second face and strip of a specified width, which enable the apparatus of the invention to provide spheroidal particles from the chopping step without any additional spheroidal shaping step. The Examiner has not even attempted to show how the cited references disclose or suggest these limitations of claim 8, and has therefore failed to make a *prima facie* showing of the obviousness of claim 8.

Moreover, the Examiner's questioning of how chopping alone could provide spheroidal particles (in the Section 112 rejection at page 1 of the Office Action) is evidence of the non-obviousness of the invention.

As indicated page 12, lines 5-6 of the specification, the spheroidal shape of the particles is essential for obtaining effective coating. But, as emphasized at page 6, lines 2-3, of the specification, "spheroidal shaping constitutes an additional step generating additional costs." The invention is based in part on the discovery by Applicants that "...it is possible to obtain the particles in accordance with the invention directly in spheroidal form at the exit from the die provided that the cutters in the chopping device at the exit from the die have the shape described later and shown in figures 1 and 2." This feature of the claimed invention is contrary to the conventional teachings in the art, such as described in the Background section of Oshlack et al. at page 5, lines 4-6, which states that particles ("pellets") chopped from extruded filaments must be "fed to a spheronizer" after the chopping step.

Claim 10 is directed to an improved method of making spheroid particles intended to be used for preparing tablets, wherein the improvement comprises providing a maturing step after

the step of forming a mixture of the active substance and the thermoplastic material and before the step of introducing the mixture into a kneading area of an extruding machine for extrusion.

The Examiner acknowledges that Oshlack et al. fails to disclose the maturing step of claim 10, and cites Martin et al. in an attempt to remedy this deficiency of Oshlack et al. This combination of reference teachings is said to be based on the following reasoning:

Accordingly, it would have been obvious to one of ordinary skills in the art to prepare particulates of an active agent using melt extrusion technique as disclosed by Oshlack to provide a sustained release active substance (page 6 lines 1-5) and combine it with Martin's disclosure to age the blend and adjust the temperature and period of aging according to the active substance included in the blend, the motivation would be the disclosure of Martin that the heat aging was found to improve the blend's flex-fatigue resistance.

This reasoning is not relevant, as Martin et al. is improperly applied non-analogous art, which is not in the same field as the present invention and is not pertinent to the problems addressed by the claimed invention. See MPEP 2141.01(a).

In re Clay, 966 F.2d 656, 23 USPQ2d 1058 (Fed. Cir. 1992) clearly suggests that the scope of the field of endeavor must be narrowly defined. In *Clay*, the Federal Circuit found that although both the prior art reference and the invention at issue related to the petroleum industry, the two were not in the same field of endeavor because the former related to the field of crude petroleum extraction, whereas the latter related to the field of refined liquid hydrocarbon storage. *Id.*

Similarly, one of ordinary skill in the pharmaceutical manufacturing art would not have considered Martin et al., a reference relating to extruded filaments for floor matting and abrasive articles (see Abstract), to be within his or her field of endeavor.

Furthermore, Martin et al. is not reasonably pertinent to the problem addressed by the invention. The maturing step of the claimed invention “yields particles which have an active principle release curve which is stabilized.” Specification at page 4, lines 20-21. Martin et al., on the other hand, teaches that aging improves the flex-fatigue resistance of filaments used for preparing floor matting and abrasive articles (Abstract). Flex-fatigue resistance is not a property relevant to particles for making pharmaceutical tablets, and certainly suggests nothing regarding the release of active principle from particles.

Thus, Martin et al. is improperly combined, non-analogous art that would not have been considered relevant to one of ordinary skill in the art addressing the problems addressed by the subject invention.

Accordingly, reconsideration and withdrawal of the obviousness rejection of claim 8 and 10 are respectfully requested.

New claim 11 further distinguishes over the applied references by limiting the method of claim 10 to the use of the cutters specified therein, which enable the method to provide spheroidal particles during the chopping step without any additional spheroidal shaping step. Regardless of whether the proposed combination of reference teachings is properly applied, the references do not teach the unobvious method of providing spheroidal particles by a chopping step.

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

Application No. 09/402,564
Amendment Dated 2/12/2007
Reply to Office Action of 10/12/06

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

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February 12, 2007

Please charge or credit our
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